## REMARKS

Reconsideration and withdrawal of the rejections of the application is respectfully requested in view of the remarks and amendments herein.

## I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 11-25 are now pending. Claims 21-25 are amended herein, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that these claims are and were in full compliance with the requirements of 35 U.S.C §112. In addition, the amendment and remarks herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§101, 102, 103 or 112; but rather the amendments and remarks herein are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Support for the amended claims is found throughout the specification.

## II. THE OBJECTIONS TO THE CLAIMS ARE OVERCOME

Claim 24 was objected to because of a misspelling. It is respectfully asserted that the amendment to claim 24 herein remedies this inadvertent error. Additionally, claim 24 was objected to because the acronym of cytomegalovirus as used in the claim is incorrect. Applicants respectfully disagree, and direct the Examiner's attention to U.S. Patent No. 6,348,196, the parent of the present application. The allowed claims of U.S. Patent No. 6,348,196 use the same phrasing as the currently pending claims, thereby attesting to their patentability in their present form. Accordingly, reconsideration and withdrawal of the objections to the claims is respectfully requested.

## III. THE REJECTIONS UNDER 35 U.S.C. §112 ARE OVERCOME

Claims 21-25 were rejected under 35 U.S.C. §112, first paragraph, because the specification is allegedly not enabling for the expression of FIV in any feline host cell. And, claims 21-25 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being

indefinite for failing to recite appropriate method steps. The rejections are traversed and will be addressed in turn.

35 U.S.C. §112, first paragraph, requires that the specification describe how to make and use the invention. 35 U.S.C. §112, first paragraph, recites, in pertinent part:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same[.]

A patent claim is invalid if it is not, *inter alia*, supported by an enabling disclosure. The test for enablement requires a determination of whether any person skilled in the art can make and use the invention without undue experimentation. *See In re Wands*, 858 F.2d 731, 8 U.S.P.Q.2d 1400, (Fed. Cir. 1988). The factors involved in determining whether there is sufficient evidence to support a finding of enablement include, among others, (1) the breadth of the claims, (2) the nature of the invention, (3) the state of the prior art, (4) the level of one of ordinary skill, (5) the level of predictability in the art, (6) the amount of direction provided by the inventor, (7) the existence of working examples, and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *See Wands*, 858 F.2d at 737, 8 U.S.P.Q.2d at 1404.

Applying the law to the instant facts, claims 21-25 are enabled. The claims relate to methods of inducing in a feline host an immunological response against feline immunodeficiency virus comprising, *inter alia*, administering to the feline host at least one plasmid.

The Office Action states that the breadth of the current claims is unreasonable, encompassing the expression FIV nucleic acids in any feline host cells. Applicants respectfully disagree.

As described above, the present invention relates to methods of inducing in a feline host an immunological response against FIV, wherein the method comprising administering to the feline host at least one plasmid that contains, and expresses *in vivo* in a feline host cell, nucleic acid molecule(s) having sequence(s) encoding feline immunodeficiency virus env protein, or gag protein, or pro protein, or gag and pro proteins, or env and gag and pro proteins. In order to make and use the present invention, one of skill in the art must have sufficient guidance to prepare the claimed plasmids and to administer such plasmids to a feline host. The administration of the plasmids would then result in the expression of the nucleic acid molecules *in vivo* in a feline host

cell, without any experimentation on the part of the skilled artisan. The uptake of the plasmids by the feline host cell, and the expression of the nucleic acids in such cells, is a direct result of the administration of the plasmids, and, it is respectfully submitted that the present specification provides amble guidance to the skilled artisan in order for the artisan to prepare and administer said plasmids without the need for undue experimentation.

Furthermore, as the second rejection under 35 U.S.C. §112 indicated that the Examiner was unclear as to whether the plasmids were to be introduced into the host cell, such that the host cell was then administered to the host feline, it is respectfully submitted that the amendments herein serve to clarify the methods such that the present invention relates to methods wherein at least one plasmid is administered to the feline host. Therefore, as the only interaction of the plasmid with the feline host cell occurs in vivo, the situation does not arise wherein the skilled artisan would be required to identify and isolate a specific host cell, such that the plasmid could then be introduced into the host cell. Rather, as the method only involves the administration of at least one plasmid, the interactions of the plasmid and the host cell occurs in vivo, and does not require any intervention on the part of the skilled artisan that would require information or knowledge additional to that which was provided in the specification.

For these reasons, reconsideration and withdrawal of the rejection of claims 21-25 under 35 U.S.C. §112, first paragraph, is respectfully requested.

Turning to the rejection of claims 21-25 under 35 U.S.C. §112, second paragraph, it is respectfully submitted that the amendments to the claims herein serve to clarify the intended method of inducing an immune response. As is evident from the amended claims, the present invention relates to methods of inducing in a feline host an immunological response against feline immunodeficiency virus comprising administering to the feline host at least one plasmid wherein the plasmid contains, and expresses *in vivo* in a feline host cell, the recited nucleic acid molecule(s).

Accordingly, as the amendments herein have rendered the rejection moot, reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. §112, second paragraph, is respectfully requested.

## IV. THE ART REJECTIONS ARE OVERCOME

Claims 21, 24 and 25 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Wardley et al. (WO 95/30019). Claims 22, 23 and 25 were also rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Wardley as applied to claims 21, 24 and 25 above, and further in view of Mazzara et al. (U.S. Patent 5,804,196). The rejections are respectfully traversed and will be addressed collectively.

The claims have been amended herein such that the present invention relates to methods of inducing in a feline host an immunological response against feline immunodeficiency virus comprising administering to the feline host at least one plasmid wherein the plasmid contains, and expresses *in vivo* in a feline host cell, nucleic acid molecule(s) having sequence(s) encoding feline immunodeficiency virus env protein, or gag protein, or pro protein, or gag and pro proteins, or env and gag and pro proteins.

It is respectfully asserted that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention. *See Lewmar Marine Inc. v. Barient Inc.,* 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Second, the prior art must contain an enabling disclosure. *See Chester v. Miller,* 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). A reference contains an enabling disclosure if a person of ordinary skill in the art could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself in possession of the invention. *See In re Donohue*, 226, U.S.P.Q. 619, 621 (Fed. Cir. 1985).

Turning to obviousness, it is also respectfully asserted that it is well-settled that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). Further, "obvious to try" is not the standard under 35 U.S.C. §103. *In re Fine,* 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification." Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, **both the suggestion of the claimed invention and the expectation of success**

**must be founded in the prior art, and not Applicants' disclosure**. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

Against this background, Wardley does not anticipate the instant invention. Nor does Wardley, when combined with Mazzara, render the instant invention unpatentable under Section 103.

Again, the present invention relates to methods of inducing in a feline host an immunological response against feline immunodeficiency virus comprising, *inter alia*, administering to the feline host at least one plasmid.

Wardley relates to vaccines containing DNA sequences encoding FIV gag protein and FIV env protein, wherein the DNA sequences are contained and expressed by an expression system. Wardley only relates to viral vectors or subunit vaccines. Nowhere in Wardley is it described, taught or suggested that the DNA may be in the form of a plasmid that can be directly provided to the feline host. Rather, the only mention of plasmids found in Wardley relates to the use of plasmids in the construction of the expression systems that were ultimately used in the making of the vaccines. Wardley does not teach or suggest the use of the plasmid itself in the vaccine, nor would Wardley, as it relates only to viral vector or subunit vaccines, provide any suggestion of modifying Wardley plasmids in the vaccines.

In contrast, the present invention relates to the administration of at least one plasmid to the feline host in order to induce the immunological response. As such methods and uses of plasmids are not taught or suggested by Wardley, the reference fails to include **all** of the elements of the claimed invention, and thus the rejection is improper and must be withdrawn.

Turning to the obviousness rejection, it is respectfully submitted that Mazzara fails to remedy the deficiencies of Wardley. Mazzara relates to a recombinant fowlpox viral vector that expresses the env, gag and pol genes of, *inter alia*, FIV. However, Mazzara does not teach or suggest the administration of at least one plasmid that contains such nucleic acid molecules. Both Wardley and Mazzara only describe viral vectors or subunit vaccines. One of skill in the art would recognize that viral vectors are quite different from plasmids, and neither Wardley or Mazzara, alone or in combination, would provide the skilled artisan with any suggestion or motivation to modify Wardley or Mazzara to use plasmids in the vaccines. Accordingly, the combination of Wardley and Mazzara is still insufficient to render the present invention obvious as neither Wardley nor Mazzara, either alone or in combination, would provide one of skill in the

art with the incentive and expectation of success to administer at least one plasmid to induce an immunological response in a host feline. Therefore, the obviousness rejection is also improper and should be withdrawn.

Consequently, reconsideration and withdrawal of the rejections under 35 U.S.C. §§ 102(b) and 103(a) is respectfully requested in view of the remarks and amendments herein.

## REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, an interview with the Examiner is respectfully requested, prior to issuance of any paper other than a Notice of Allowance; and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

## CONCLUSION

In view of the remarks and amendments herewith and those of record, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance, or an interview at a very early date with a view to placing the application in condition for allowance, are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully Submitted,

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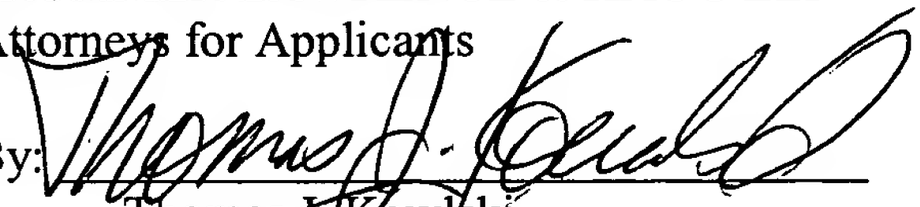
By: 

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